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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,888	11/20/2000	Andrew C. Hiatt	030905.0002.CON2	6791

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/717,888	Hiatt et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *2/28/03; 1/29/03* .

2a) [X] This action is **FINAL**. 2b) [ ] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *80 and 82* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *80 and 82* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment D, paper No.15, filed 2/28/03. Claims 54-79, and 81 have been canceled. Claims 80, and 82 are pending before the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 80, and 82 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 8/29/02. Applicants argue that the specification clearly describes the claims. In addition, applicant refer the Office to Table 1 wherein rabbit pIgR and examples of analogous regions are listed. Still further, with respect to claim 82, applicants argue that first the specific plant or plants should not be recited because immunoglobulin and a protection protein was co-expressed in alfalfa, tomato, tobacco, and *Arabidopsis* plants. Moreover, applicants assert, claim 82 is an immunoglobulin claim, and not a method claim, nor a product-by-process claim, thus, no necessary steps need to be recited. Applicant's argument as part of amendment D, Paper NO. 9, filed 2/28/03 has been considered fully, but they are not persuasive. At the onset applicants are reminded, although the claims are interpreted in light of the specification, limitations from the specification are not read into the

claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The intended metes and bounds of "protection protein"is not defined. It is not clear whether this "protection protein" is two amino acid long or 100 or 1000, and when one looks at the specification for understanding of the claim, the specification does not set forth clear boundaries for the "protection protein", hence, the claim is vague and indefinite. What applicants deem to be clear recitation is nothing but broad recitation of various groups of proteins, such as proteins that according to Applicants provide "enhanced resistance." What does this mean? How can one be appraised of the claim boundary with this type of recitation. The term "derived" as stated previously is a relative term, which renders the claim indefinite, the specification does not provide a standard for ascertaining the requisite degree. The term "derived" is not defined by the claim. The intended metes and bounds of the protein that is "derived" from a "polyimmunoglobulin receptor" is not defined. Moreover, the intended polyimmunoglobulin receptor is not defined. Still further, applicants refer the Office to Table 1, but Table 1 has no information that is relevant. No worthy information can be deciphered form the said Table 1, since the relevant information is omitted.

Moreover, with respect to claim 82, the type of plant is very important, since the different plants would produce immunoglobulines that have different glycocylation patterns and/or their byproduct is /are different one from the other. The immunoglobulin from a tobacco plant is different than the antibody that is produced from a banana. In addition, claim 82 is indeed a product-by-process claim. The claim recites, " immunoglobulin" (product) ..... is plant

produced (process). Hence, the conditions and method steps that would permit the production of immunoglobulin in a specif plant should be clearly recited. If claim 82 is not a product by process claim then what is the difference between the product of claim 80, and 82? The rejection is maintained.

Double Patenting

Claims 80, and 82 are rejected under 35 U.S.C. 101, for reasons of record advanced in the previous Office Action mailed 8/29/02. Applicants argue that claims cannot be literally infringed by an antibody recited in the U.S. Patent No. 6,303,341 B1. Applicant's argument as part of amendment D, Paper NO. 9, filed 2/28/03 has been considered fully, but they are not persuasive. Applicants tend to undermine the extent of patent protection they have been awarded in the 6,303,341 B1. All possible permutation are present in the claims of ,341 patent. The Office pointed to main claim 1, applicants cannot ignore all the claims that are dependent from claim 1 which would cover all possible scenarios, including the scenarios that would fall within claims 80, and 82. In other words, there is no embodiment that falls within the scope of claims 80, and 82, but not the already allowed claims. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 80, and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehner et al (WO 88/06455) or the US patent no. 4,594,244, for reasons of record advanced in the previous

Office Action mailed 8/29/02. Applicants argue that Lehner et al teaches an antibody specific for S. Sorbrinus serotype d and methods of making the antibody. Applicants assert that no-where in the reference or the patent Lehner et al describes a protection protein derived from a polyimmunoglobuline receptor. Applicants conclude that requirement under 102 (b) has not been me. Applicant's argument as part of amendment D, Paper NO. 9, filed 2/28/03 has been considered fully, but they are not persuasive. As was clearly indicated the claims are directed to a product (emphasis added), as Applicants point out the product disclosed by Lehner et al is capable of doing the same function as applicants own claimed product, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). There are no head to head study present in the specification showing a difference between the antibodies disclosed in the above reference and the Applicants' immunoglobulin. After all if some one adds a small innocuous region i.e spacer protein to a known antibody, they haven't disclosed a new antibody. This is similar to the case in hand. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. The rejection is/are maintained.

Claim 80 is rejected under 35 U.S.C. 102(b) as being anticipated by Schlom US Patent No. 5,183,756, for reasons of record advanced in the previous Office Action mailed 8/29/02. Applicants argue Schlom teaches a monoclonal antibody for treating gasterointenstinal cancer.

Applicants add the antibody maybe conjugated to a agent. Applicants assert that conjugation of a protein derived from pIgR that protects it form degradation and denaturation is not described. Applicants conclude that requirement under 102 (b) has not been me. Applicants' argument as part of amendment D, Paper NO. 9, filed 2/28/03 has been considered fully, but they are not persuasive. None of the limitations that Applicants recite is present in the claim. There is nothing in the claim that says the so called "protection protein" is protecting the immunoglobulin from "degradation" and "denaturation". Moreover, applicants assertion that the agents disclosed by the above cited patent would not "protect" is deemed to be an unsupported assertion. No evidence has been provided that once the antibody is conjugated to a toxin or a second antibody the toxin or the second antibody would not act as a protective protein. Still further, Applicants assertion is factually misplaced, because the antibodies taught by Schlom are targeting the gastrointestinal epithelium, which means the antibody is transported via immunoglobulin receptor (pIgR). The pIgR binds and the antibody is transported to the opposing cell surface. Hence, the antibodies of Schlom would also be protected from "degradation" due to naturally binding to the pIgR on the epithelium cells. As evidence see the reference (CX) provided by the Applicants in the 1449 submitted 6/25/01, which teaches the mechanism that is involved. The Office contends that the antibodies taught and claimed by the above cited patent are inherently protected by the pIgR upon binding. Moreover, what if the toxin of claim 14 shares amino acid regions with the pIgR, wouldn't that anticipate the now broad product? What if the "derived" protein has shared identity with limitations of claim 14 of Schlom's patent, wouldn't the antibody be the same as now

product? The derived protein can be any where from 2 amino acids long to 1000 amino acids long. There is/are no head to head study present that shows the now claimed product is different than the one taught by the above cited patent. It is concluded that the product of cited patent do indeed anticipate the product now being claimed. Applicants should keep in mind absent clear and concise limitations the broadest possible interpretation has been awarded. The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Still further, the intended use of a well known product does not carry patentable weight. The rejection is maintained.

Claim 80 is rejected under 35 U.S.C. 102(e) as being anticipated by Lehner et al (5,854,402), for reasons of record advanced in the previous Office Action mailed 8/29/02. Applicants argue the cited patent does not teach a protection protein derived from a polyimmunoglobuline receptor. Applicant's argument as part of amendment D, Paper NO. 9, filed 2/28/03 has been considered fully, but they are not persuasive. As was clearly indicated the claim is directed to a product (emphasis added). If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). There are no head to head study present in the specification showing a difference between the antibodies disclosed in the above patent and the Applicants' immunoglobulin. After all if some one adds a small innocuous region i.e spacer protein to a known antibody, they haven't disclosed a new antibody. This is similar to the case in

hand. There are no evidence presented that indicates the prior art product is not capable of performing the same use. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. The rejection is maintained.

Claim Rejections - 35 USC § 103

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehner et al (WO 88/06455), and Hiatt et al (US Patent No. 5,202,422, 4/13/1993), for reasons of record advanced in the previous Office Action mailed 8/29/02. Applicants argue that Lehner et al does not describe an immunoglobulin having a protection protein derived from pIgR and Hiatt et al does not cure this defect, thus the combined reference do not meet the requirements of section 103. Applicant's argument as part of amendment D, Paper NO. 9, filed 2/28/03 has been considered fully, but they are not persuasive. The limitation of pIgR has been treated as a design choice, unless the proof of criticality is proven. There are no unexpected results presented in the specification over the teaching of the prior art. The product of Lehner et al are made to resist degradation, and there is nothing in the specification which indicates the modification of the cited antibody by adding any and all pieces of pIgR is superior to what prior art has already taught. Modifying a well known antibody by adding a protein is considered a design choice. Applicants should point to unexpected results. The rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salami whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James House, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salami

3/14/2003